

UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF TEXAS

PUBLIC HEALTH AND MEDICAL  
PROFESSIONALS FOR TRANSPARENCY,

Plaintiff,

-against-

FOOD AND DRUG ADMINISTRATION,

Defendant.

Civil Action No. \_\_\_\_\_

**COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF**

Plaintiff, as for its Complaint regarding a Freedom of Information Act request against the above-captioned Defendant, alleges as follows:

**INTRODUCTION**

1. Until only a few weeks ago, all coronavirus vaccines available in the United States were only authorized for emergency use by the U.S. Food and Drug Administration (the “**FDA**”).<sup>1</sup>

2. On August 23, 2021, the FDA approved the Pfizer-BioNTech COVID-19 Vaccine, marketed as Comirnaty (the “**Pfizer Vaccine**”) for individuals 16 years of age and older.<sup>2</sup>

3. Although the FDA asserts that the Pfizer Vaccine “meets the high standards for safety, effectiveness, and manufacturing quality the FDA requires of an approved product[.]”<sup>3</sup> numerous public health officials, media outlets, journalists, scientists, politicians, public figures, and others with large social or media platforms have publicly raised questions regarding the sufficiency of the data and information, the adequacy of the review, and the appropriateness of the

<sup>1</sup> <https://www.bmj.com/content/373/bmj.n1244> (last visited 9/5/2021).

<sup>2</sup> <https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine> (last visited 9/5/2021).

<sup>3</sup>*Id.*

analyses relied upon by the FDA to license the Pfizer Vaccine.

4. PHMPT is an organization made up of public health professionals, medical professionals, scientists, and journalists. PHMPT exists for the sole purpose of disseminating to the public the data and information in the biological product files for each of the COVID-19 vaccines.

5. In furtherance of its mission, and in an effort to ensure that the FDA acts in furtherance of its commitment to transparency,<sup>4</sup> PHMPT seeks to obtain the data and information relied upon by the FDA to license the Pfizer Vaccine. The importance of releasing to the public this information is also recognized under federal law which provides that: “After a license has been issued, the following data and information in the biological product file are immediately available for public disclosure unless extraordinary circumstances are shown: (1) All safety and effectiveness data and information. (2) A protocol for a test or study . . .” 21 C.F.R. § 601.51(e).

6. PHMPT therefore issued a request to the FDA pursuant to the Freedom of Information Act (5 U.S.C. § 552, as amended) (“**FOIA**”) for “[a]ll data and information for the Pfizer Vaccine enumerated in 21 C.F.R. § 601.51(e)<sup>5</sup> with the exception of publicly available reports on the Vaccine Adverse Events Reporting System.<sup>6</sup>” (the “**FOIA Request**”).

7. The medical and scientific community and the public have a substantial interest in reviewing the data and information underlying the FDA’s approval of the Pfizer Vaccine.

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<sup>4</sup> <https://www.fda.gov/about-fda/transparency> (last visited 9/5/2021).

<sup>5</sup> 21 C.F.R. § 601.51(e) provides that after a biological product is licensed, the following information shall be made available for immediate disclosure absent extraordinary circumstances: “(1) All safety and effectiveness data and information. (2) A protocol for a test or study . . . (3) Adverse reaction reports, product experience reports, consumer complaints, and other similar data and information . . . (4) A list of all active ingredients and any inactive ingredients . . . (5) An assay method or other analytical method . . . (6) All correspondence and written summaries of oral discussions relating to the biological product file . . . (7) All records showing the manufacturer’s testing of a particular lot . . . (8) All records showing the testing of and action on a particular lot by the [FDA].”

<sup>6</sup> For the avoidance of doubt, the FOIA Request includes but is not limited to all of the data and information in the biological product file, as defined in 21 C.F.R. § 601.51(a), for the Pfizer Vaccine enumerated in 21 C.F.R. § 601.51(e) with the exception of publicly available reports on the Vaccine Adverse Events Reporting System.

Reviewing this information will settle the ongoing public debate regarding the adequacy of the FDA's review process. Releasing this data should also confirm the FDA's conclusion that the Pfizer Vaccine is safe and effective and, thus, increase confidence in the Pfizer Vaccine. The public's need for this information is urgent given the fact that COVID-19 vaccines are being mandated to individuals across the country by federal, state, and local governments as well as private businesses.

8. In an effort to disseminate the requested information to the public as expeditiously as possible, given the time sensitive nature of the issue, PHMPT requested expedited processing of the FOIA Request pursuant to 5 U.S.C. § 552(a)(6)(E)(v)(II).

9. On September 9, 2021, the FDA denied PHMPT's request for expedited processing on the basis that PHMPT did "not demonstrate[] a compelling need that involves an imminent threat to the life or physical safety of an individual" or "that there exists an urgency to inform the public concerning actual or alleged Federal Government activity." PHMPT brings this action to challenge the FDA's determination and seeks an order compelling the FDA to produce responsive records on an expedited basis.

### **PARTIES**

10. Public Health and Medical Professionals for Transparency is a not-for-profit organization with an office located at 1090 Texan Trail, Suite 534, Fort Worth, Texas, 76051.

11. PHMPT's members include:

- a. **Aaron Kheriaty, MD**  
Professor of Psychiatry, UCI School of Medicine  
Director, Medical Ethics Program, UCI Health
- b. **Harvey Risch, MD, PhD**  
Professor of Epidemiology  
Yale School of Public Health
- c. **Peter A. McCullough, MD, MPH, FACP, FACC,**  
FCCP, FAHA, FNKF, FNLA, FCRSA

- d. **Carole H Browner, PhD, MPH**  
Distinguished Research Professor  
UCLA David Geffen School of Medicine
- e. **Peter Doshi, PhD**  
Associate Professor, Pharmaceutical Health Services Research  
University of Maryland School of Pharmacy  
Baltimore, Maryland, U.S.A.
- f. **Linda Wastila, BSPHarm, MSPH, PhD**  
Professor, Pharmaceutical Health Services Research  
University of Maryland School of Pharmacy
- g. **Andrew Bostom, MD, MS**  
Associate Professor of Family Medicine (Research)  
The Warren Alpert Medical School of Brown University
- h. **Erick H. Turner, MD**  
Associate Professor  
Oregon Health & Science University
- i. **Aditi Bhargava, PhD**  
Professor Emerita  
Department of ObGyn and Reproductive Sciences University of California  
San Francisco
- j. **Joseph A. Ladapo, MD, PhD**  
Associate Professor of Medicine  
Division of General Internal Medicine and Health Services Research  
David Geffen School of Medicine at UCLA
- k. **Gabe Vorobiof, MD FACC FASE**  
Director, Adult Non-Invasive Cardiology Laboratories  
UCLA Cardiovascular Center  
Associate Clinical Professor of Medicine  
David Geffen School of Medicine at UCLA
- l. **Donald W. Light, PhD**  
Professor of Comparative Health Policy and Psychiatry  
Rowan University School of Osteopathic Medicine  
Glassboro, New Jersey, U.S.A.
- m. **Allyson M Pollock, MBChB, FRCPH, FRCP (Ed) FRCGP**  
Clinical Professor of Public Health  
Institute of Health and Society, Newcastle University  
Newcastle upon Tyne, United Kingdom
- n. **Anthony J. Brookes, PhD**  
Professor of Genetics  
University of Leicester  
Leicester, United Kingdom
- o. **László G. Boros, MD**  
Scientific Advisor  
SIDMAP, LLC and the Deutenomics Science Institute
- p. **Angela Spelsberg, MD, SM**  
Comprehensive Cancer Center Aachen

- Aachen, Germany
- q. **Christine Stabell Benn, MD, PhD, DMSc**  
Professor of Global Health  
University of Southern Denmark  
Copenhagen, Denmark
- r. **Peter Aaby, MSc, DMSc**  
Head of Bandim Health Project, Guinea-Bissau  
University of Southern Denmark  
Copenhagen, Denmark
- s. **Ulrich Keil, MD, PhD, FRCP (London)**  
Professor Emeritus  
University of Muenster  
Muenster, Germany
- t. **Barbara Mintzes, BA, MSc, PhD**  
Associate Professor, School of Pharmacy  
The University of Sydney  
Sydney, Australia
- u. **David Healy, MD FRCPsych**  
Professor of Psychiatry  
McMaster University  
Ontario, Canada
- v. **Tom Jefferson, MD MRCGP FFPHM**  
Senior Associate Tutor  
University of Oxford
- w. **Byram W. Bridle, PhD**  
Associate Professor of Viral Immunology  
Department of Pathobiology  
University of Guelph, Ontario
- x. **Peter C. Gøtzsche, Professor, DrMedSci, MD, MSc**  
Director  
Institute for Scientific Freedom  
Copenhagen, Denmark
- y. **Janice E. Graham, PhD, FRSC, FCAHS**  
Division of Infectious Diseases  
University research Professor  
Dalhousie University
- z. **Justin Lee**  
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Dept. Family and Community Medicine  
University of Toronto

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Biomedical Researcher  
University of Toronto
- ee. **Prof. David Menkes**  
Associate Professor  
University of Auckland
- ff. **Dr. Peter Abdelmalak**  
Adjunct Professor  
McMaster University

12. The FDA is an agency within the Executive Branch of the United States Government, organized within the Department of Health and Human Services. The FDA is an agency within the meaning of 5 U.S.C. § 552(f).

### **JURISDICTION AND VENUE**

13. This Court has jurisdiction over this action pursuant to 5 U.S.C. § 552(a)(4)(B) and 28 U.S.C. § 1331. Venue is proper within this District pursuant to 5 U.S.C. § 552(a)(4)(B) and 28 U.S.C. § 1391.

### **FACTS**

#### **A. FDA Approval of the Pfizer Vaccine**

14. On August 23, 2021, the FDA approved the Pfizer Vaccine for individuals 16 years of age and older.<sup>7</sup>

15. There is an ongoing, public national debate regarding the adequacy of the data and information, and analyses of same, relied upon by the FDA to license the Pfizer Vaccine.

16. On the one hand, there are numerous public health officials, media outlets, journalists, scientists, politicians, public figures, and others with large social or media platforms that have declared that the data and information underlying the licensure of the Pfizer Vaccine is more than sufficient for licensure.

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<sup>7</sup> <https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine> (last visited 9/5/2021).

17. For example, in a press release issued on August 23, 2021, acting FDA Commissioner Janet Woodcock stated that “the public can be very confident that [the Pfizer Vaccine] meets the high standards for safety, effectiveness, and manufacturing quality the FDA requires of an approved product.”<sup>8</sup>

18. Peter Marks, the director of FDA’s Center for Biologics Evaluation and Research, made similar remarks, stating that

[The FDA’s] scientific and medical experts conducted an incredibly thorough and thoughtful evaluation of [the Pfizer Vaccine]. We evaluated scientific data and information included in hundreds of thousands of pages, conducted our own analyses of [the Pfizer Vaccine’s] safety and effectiveness, and performed a detailed assessment of the manufacturing processes, including inspections of the manufacturing facilities[.]<sup>9</sup>

19. Peter Marks further stated that “although [the FDA] approved [the Pfizer Vaccine] expeditiously, it was fully in keeping with [the FDA’s] existing high standards for vaccines in the U.S.”<sup>10</sup>

20. President Biden also stated that the FDA’s approval meets the “gold standard.”<sup>11</sup>

21. Even prior to FDA approval of the Pfizer Vaccine, government officials, public health authorities, and medical professionals repeatedly claimed that COVID-19 vaccines are “safe and effective.”<sup>12</sup>

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<sup>8</sup> <https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine> (last visited 9/8/2021).

<sup>9</sup> *Id.*

<sup>10</sup> *Id.*

<sup>11</sup> <https://www.cbsnews.com/news/biden-address-covid-19-vaccine-pfizer-fda-approval-watch-live-stream-today-2021-08-23/> (last visited 9/8/2021).

<sup>12</sup> See, e.g., <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/safety-of-vaccines.html#:~:text=COVID%2D19%2Dvaccines%2Dare%2Dsafe,vaccine%2Das%2Dsoon%2Das%2Dpossible> (last visited 9/8/2021). See also <https://www.hhs.gov/> (“COVID-19 vaccines are safe, effective, and free”) (last visited 9/8/2021); <https://www.who.int/news-room/feature-stories/detail/vaccine-efficacy-effectiveness-and-protection> (“COVID-19 vaccines have proven to be safe, effective and life-saving.”) (last visited 9/8/2021); <https://www.doh.wa.gov/Emergencies/COVID19/VaccineInformation/SafetyandEffectiveness> (“COVID-19 vaccines are safe”) (last visited 9/8/2021); <https://www.wlns.com/news/gov-whitmer-and-dr-khaldun-respond-to-the-fda-approval-of-pfizers-covid-19-vaccine/> (quoting Governor Whitmer referring to the Pfizer Vaccine as a “safe, effective COVID-19

22. On the other hand, numerous public health officials, media outlets, journalists, scientists, politicians, public figures, and others with large social or media platforms have publicly raised questions regarding the sufficiency of the data and information, adequacy of the review, and appropriateness of the analyses relied upon to license the Pfizer Vaccine, including a number of the scientists and journalists that are members of PHMPT.

23. For example, on June 1, 2021, a group of 27 clinicians and scientists, including professors from Harvard Medical School and the UCLA School of Public Health, and members of PHMPT, filed a Citizen Petition<sup>13</sup> with the FDA, claiming that the available evidence for licensure of the Pfizer Vaccine “is simply not mature enough at this point to adequately judge whether clinical benefits outweigh the risks in all populations.”<sup>14</sup>

24. Separately, Professor Peter Doshi, a PHMPT member, has publicly questioned the lack of transparency regarding the vaccine approval process,<sup>15</sup> which Peter Marks publicly disputed.<sup>16</sup> For example, Peter Doshi publicly claimed that the FDA’s EUA review of the Pfizer Vaccine “seem[ed] wholly inadequate” because it “assigned only a single reviewer in each of two key scientific disciplines (clinical and statistics) to do the work in three weeks that usually takes months to do.”<sup>17</sup> In response, Peter Marks asserted that the reviewers Doshi referred to “are simply the leads for each review discipline” but failed to identify a single additional individual involved

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vaccine”) (last visited 9/8/2021).

<sup>13</sup> <https://www.regulations.gov/document/FDA-2021-P-0521-0001> (last visited 9/8/2021).

<sup>14</sup> See <https://blogs.bmj.com/bmj/2021/06/08/why-we-petitioned-the-fda-to-refrain-from-fully-approving-any-covid-19-vaccine-this-year/> (last visited 9/8/2021).

<sup>15</sup> See <https://blogs.bmj.com/bmj/2021/08/23/does-the-fda-think-these-data-justify-the-first-full-approval-of-a-covid-19-vaccine/> (last visited 9/8/2021); <https://blogs.bmj.com/bmj/2021/01/04/peter-doshi-pfizer-and-modernas-95-effective-vaccines-we-need-more-details-and-the-raw-data/> (last visited 9/8/2021); <https://blogs.bmj.com/bmj/2020/11/26/peter-doshi-pfizer-and-modernas-95-effective-vaccines-lets-be-cautious-and-first-see-the-full-data/> (last visited 9/8/2021).

<sup>16</sup> <https://www.statnews.com/2020/12/17/did-the-fda-understaff-its-review-of-the-pfizer-biontech-vaccine/> (last visited 9/8/2021).

<sup>17</sup> *Id.*



in the review.<sup>18</sup>

25. Peter Doshi has also questioned the adequacy of the data on the basis that the Pfizer Vaccine is only “13 months into the still ongoing, two year pivotal trial, with no reported data past 13 March 2020, unclear efficacy after six months due to unblinding, evidence of waning protection irrespective of the Delta variant, and limited reporting of safety data.”<sup>19</sup>

26. Andrew Kheriaty, professor of psychiatry at UCI School of Medicine, Director of the Medical Ethics Program at UCI Health,<sup>20</sup> and also a member of PHMPT, has also questioned the FDA’s approval process. For example, in an article published in the Wall Street Journal, Dr. Kheriaty questioned the need for student vaccination requirements based on, among other things, a review<sup>21</sup> by the FDA’s Vaccines and Related Biological Products Advisory Committee (“VRBPAC”) that indicates a risk of heart inflammation after vaccination.<sup>22</sup>

27. Government officials have raised similar concerns about the lack of transparency in the review process, arguing that it is “essential” for the FDA to, among other things, “make the data generated by clinical trials and supporting documents submitted to the FDA by developers available to the public[.]”<sup>23</sup> Despite all eyes on the COVID-19 vaccines and calls for transparency regarding the FDA’s actions, the FDA did not convene its advisory group, VRBPAC, to have a public meeting prior to licensure. Those interested were denied the opportunity to both hear discussion about the data and to offer public comment about same.

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<sup>18</sup> *Id.*

<sup>19</sup> <https://blogs.bmj.com/bmj/2021/08/23/does-the-fda-think-these-data-justify-the-first-full-approval-of-a-covid-19-vaccine/> (last visited 9/8/2021).

<sup>20</sup> <https://www.aaronkheriaty.com/bio> (last visited 9/8/2021).

<sup>21</sup> <https://www.fda.gov/media/150054/download> (last visited 9/8/2021).

<sup>22</sup> <https://www.wsj.com/articles/university-vaccine-mandates-violate-medical-ethics-11623689220> (last visited 9/8/2021).

<sup>23</sup> [https://www.warren.senate.gov/imo/media/doc/2020.09.14%20Letter%20to%20FDA%20re%20transparency%20in%20vaccine%20review%20process\\_.pdf](https://www.warren.senate.gov/imo/media/doc/2020.09.14%20Letter%20to%20FDA%20re%20transparency%20in%20vaccine%20review%20process_.pdf) (last visited 9/8/2021). *See also* <https://www.washingtontimes.com/news/2021/aug/23/editorial-the-coincidental-timing-of-pfizers-vacci/> (last visited 9/8/2021).

**B. Vaccine Requirements**

28. Over the objections of many, the Pfizer Vaccine is being mandated to individuals across the country by the federal government,<sup>24</sup> local governments,<sup>25</sup> public and private employers,<sup>26</sup> universities,<sup>27</sup> schools,<sup>28</sup> and various other institutions,<sup>29</sup> and many more entities are expected to follow suit.<sup>30</sup>

29. At the federal level, legislation was recently introduced that would require COVID-

<sup>24</sup> See, e.g., <https://www.natlawreview.com/article/covid-19-vaccine-added-to-requirements-green-card-processing-effective-oct-1> (last visited 9/8/2021); <https://apnews.com/article/business-health-coronavirus-pandemic-coronavirus-vaccine-4cf7451267919302de4a7b591508e80c> (last visited 9/8/2021); <https://www.forbes.com/sites/joewalsh/2021/08/09/us-military-will-require-covid-vaccinations-by-mid-september/?sh=78defacd6c9f> (last visited 9/8/2021); <https://www.whitehouse.gov/briefing-room/statements-releases/2021/07/29/fact-sheet-president-biden-to-announce-new-actions-to-get-more-americans-vaccinated-and-slow-the-spread-of-the-delta-variant/> (last visited 9/8/2021).

<sup>25</sup> See, e.g., <https://www.cnn.com/2021/08/12/us/san-francisco-vaccine-requirement/index.html> (last visited 9/8/2021); <https://www1.nyc.gov/site/doh/covid/covid-19-vaccines-keytonyc.page> (last visited 9/8/2021); <https://news.yahoo.com/orleans-now-requires-proof-vaccination-230433492.html> (last visited 9/8/2021).

<sup>26</sup> See, e.g., <https://www.cnn.com/2021/08/06/united-airlines-vaccine-mandate-employees.html> (last visited 9/8/2021); <https://sanfrancisco.cbslocal.com/2021/08/02/covid-kaiser-permanente-makes-vaccination-mandatory-for-all-employees/> (last visited 9/8/2021); <https://abcnews.go.com/Health/wireStory/walmart-mandates-vaccines-workers-headquarters-79177220> (last visited 9/8/2021); <https://www.kpbs.org/news/2021/08/17/encinitas-covid-19-vaccine-negative-test-employees/> (last visited 9/8/2021); <https://www.cnn.com/2021/08/09/covid-vaccine-mandates-sweep-across-corporate-america-as-delta-surges.html> (last visited 9/8/2021); <https://www.reuters.com/business/energy/chevron-begins-covid-19-vaccination-mandates-wsj-2021-08-23/> (last visited 9/8/2021); <https://thehill.com/policy/healthcare/569051-pfizers-full-approval-triggers-new-vaccine-mandates> (last visited 9/8/2021); <https://cvshealth.com/news-and-insights/statements/cvs-health-will-require-covid-19-vaccinations-for-clinical-and-corporate-employees> (last visited 9/8/2021).

<sup>27</sup> See <https://universitybusiness.com/state-by-state-look-at-colleges-requiring-vaccines/> (last visited 9/8/2021). See also, e.g., <https://www.nbcnews.com/health/health-news/colleges-universities-covid-vaccination-mandates-facing-pushback-n1273916> (last visited 9/8/2021); <https://www.colorado.edu/covid-19/updates/covid-19-vaccination> (last visited 9/8/2021); <https://uhs.berkeley.edu/requirements/covid19> (last visited 9/8/2021); <https://huhs.harvard.edu/covid-19-vaccine-requirement-faqs> (last visited 9/8/2021); <https://www2.gmu.edu/safe-return-campus/vaccination-requirements> (last visited 9/8/2021); <https://www.pc.pitt.edu/news/vaccine-disclosure-requirements-2021-2022-campus-housing> (last visited 9/8/2021).

<sup>28</sup> See, e.g., <https://www.npr.org/sections/back-to-school-live-updates/2021/08/20/1029837338/a-california-school-district-mandates-vaccines-for-eligible-students> (last visited 9/8/2021); <https://patch.com/massachusetts/salem/salem-school-committee-approves-vaccine-mandate-sports-band> (last visited 9/8/2021); <https://www.nbcnewyork.com/news/coronavirus/nyc-will-require-vaccination-for-high-risk-school-sports/3232745/> (last visited 9/8/2021); <https://www.nj.com/hudson/2021/08/hoboken-believed-to-be-first-in-state-to-issue-mandate-for-students-12-and-up-get-vaccine-or-face-weekly-testing.html> (last visited 9/8/2021); <https://www.mercurynews.com/2021/08/19/la-county-school-district-mandates-covid-vaccines-for-k12-kids-others-soon-may-follow/> (last visited 9/8/2021).

<sup>29</sup> See, e.g., <https://www.reuters.com/world/us/new-york-city-mandates-covid-19-vaccine-public-school-teachers-staff-mayor-2021-08-23/> (last visited 9/8/2021); <https://www.cbsnews.com/news/california-covid-vaccine-teachers-mandate/> (last visited 9/8/2021); <https://www.nytimes.com/2021/08/18/us/washington-state-teacher-vaccine-mandate.html> (last visited 9/8/2021); <https://www.governor.ny.gov/news/governor-cuomo-announces-covid-19-vaccination-mandate-healthcare-workers> (last visited 9/8/2021); <https://www.cdph.ca.gov/Programs/CID/DCDC>

19 vaccines for air travel into or out of the United States<sup>31</sup> and the Pentagon has mandated COVID-19 vaccines for all military personnel.<sup>32</sup> In addition, Present Biden recently announced vaccine mandates for all employers with 100 or more employees, all federal employees, and all employees of federal contractors.<sup>33</sup>

30. At the state level, legislation has been introduced to require COVID-19 vaccines for all post-secondary students,<sup>34</sup> all state employees,<sup>35</sup> and even for all citizens of the state.<sup>36</sup>

31. As explained by Dr. Anthony Fauci, “a flood” of vaccine mandates will follow FDA approval of a COVID-19 vaccine<sup>37</sup> and President Biden is actively encouraging “companies in the private sector to step up the vaccine requirements[.]”<sup>38</sup>

[/Pages/COVID-19/FAQ-Health-Care-Worker-Vaccine-Requirement.aspx](https://www.nytimes.com/2021/08/09/us/washington-state-workers-vaccine-mandate.html) (last visited 9/8/2021); <https://www.nytimes.com/2021/08/09/us/washington-state-workers-vaccine-mandate.html> (last visited 9/8/2021); <https://www.denvergov.org/Government/COVID-19-Information/Public-Health-Orders-Response/News-Updates/2021/Mayor-Hancock-Announces-COVID-19-Vaccine-Requirement-for-Employees> (last visited 9/8/2021); See <https://www.bostonherald.com/2021/08/19/baker-issues-vaccine-mandate-for-42000-state-employees/> (last visited 9/8/2021).

<sup>30</sup> See <https://www.mississippifreepress.org/15126/fda-fully-approves-pfizer-biontech-vaccine-mandates-to-follow/> (last visited 9/8/2021); [https://www.huffpost.com/entry/vaccine-mandates-roll-out-fda-approval\\_n\\_6123e028e4b0df3eacd5d657](https://www.huffpost.com/entry/vaccine-mandates-roll-out-fda-approval_n_6123e028e4b0df3eacd5d657) (last visited 9/8/2021); [https://www.theadvocate.com/baton\\_rouge/news/coronavirus/article\\_9befd02c-0434-11ec-b7b1-cb17d8495274.html?utm\\_medium=social&utm\\_source=twitteroladotcom&utm\\_campaign=snd](https://www.theadvocate.com/baton_rouge/news/coronavirus/article_9befd02c-0434-11ec-b7b1-cb17d8495274.html?utm_medium=social&utm_source=twitteroladotcom&utm_campaign=snd) (last visited 9/8/2021). See also <https://www.latimes.com/california/story/2021-08-26/california-lawmakers-grapple-with-statewide-covid-19-vaccine-mandate> (last visited 9/8/2021).

<sup>31</sup> <https://www.congress.gov/bill/117th-congress/house-bill/4980?q=%7B%22search%22:%5b%224980%252> (last visited 8/23/2021).

<sup>32</sup> <https://thehill.com/policy/defense/568996-pentagon-to-mandate-covid-19-vaccine-for-military> (last visited 8/23/2021).

<sup>33</sup> <https://www.whitehouse.gov/covidplan/> (last visited 9/13/2021). *See also* <https://www.cnn.com/2021/09/09/politics/joe-biden-covid-speech/index.html> (last visited 9/13/2021).

<sup>34</sup> See New York bill S6495 available at <https://www.nysenate.gov/legislation/bills/2021/S6495> (last visited 9/8/2021).

<sup>35</sup> See, e.g., <https://www.nj.com/coronavirus/2021/08/murphy-orders-vaccination-requirement-for-all-nj-state-workers-including-at-public-colleges.html> (last visited 9/8/2021).

<sup>36</sup> See New York bill A11179 available at <https://www.nysenate.gov/legislation/bills/2019/A11179>. See generally <https://eastcountytoday.net/buffy-wicks-transportation-bill-could-become-california-vaccine-passport-bill/> (last visited 9/8/2021).

<sup>37</sup> <https://www.usatoday.com/story/news/health/2021/08/06/anthony-fauci-covid-vaccine-mandates-fda-full-approval/5513121001/> (last visited 9/8/2021).

38 <https://www.msn.com/en-us/news/us/biden-urges-private-companies-to-implement-covid-19-vaccine-requirements-following-pfizer-e2-80-99s-fda-approval/ar-AANecYs?ocid=uxbndlbing> (last visited 9/8/2021). *See also* <https://www.nytimes.com/2021/08/23/us/pfizer-vaccine-mandates.html> (noting that FDA approval of the Pfizer Vaccine “is opening the way for institutions like the military, corporate employers, hospitals and school districts to announce vaccine mandates for their employees”) (last visited 8/23/2021); <https://www.msn.com/en-us/news/us/now->

32. More recently, it appears that mandates may now encompass additional booster shots of the vaccine in order to retain a “fully vaccinated” status.<sup>39</sup>

### C. The FOIA Request

33. In furtherance of PHMPT’s mission to disseminate information to the public, and in an effort to ensure that the FDA acts consistently with its commitment to transparency,<sup>40</sup> on August 27, 2021, PHMPT submitted the FOIA Request to the FDA. Pursuant to the FOIA Request, PHMPT requested that the following documents be produced on an expedited basis:

**All data and information for the Pfizer Vaccine enumerated in 21 C.F.R. § 601.51(e)<sup>41</sup> with the exception of publicly available reports on the Vaccine Adverse Events Reporting System.<sup>42</sup>**

(Exhibit A.1.)<sup>43</sup>

34. Upon submitting the FOIA Request, PHMPT immediately received confirmation that the FOIA Request was submitted successfully. (Exhibit A.2.)

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[that-a-covid-19-shot-is-fully-approved-employer-mandates-are-rolling-in-but-will-vaccination-rates-in-the-us-go-up/ar-AAANGDTy?ocid=uxbndllbing](https://www.cdc.gov/media/releases/2021/s0823-covid-19-shot-boosters.html) (last visited 8/23/2021); <https://news.yahoo.com/surgeon-general-vivek-murthy-says-205530053.html> (quoting the Surgeon General referring to vaccine mandates as “reasonable”) (last visited 8/23/2021).

<sup>39</sup> See <https://www.nbcnews.com/health/health-news/u-s-announces-plan-offer-boosters-all-americans-starting-late-n1277059> (quoting the U.S. Surgeon General stating “it is our clinical judgment that the time to lay out a plan for Covid-19 boosters is now”) (last visited 9/13/2021); <https://www.youtube.com/watch?v=ciVGAPuruoQ> at 17:21 (video of Rochelle P. Walensky, Director of the CDC, stating “we are planning for Americans to receive booster shots”) (last visited 9/13/2021).

<sup>40</sup> <https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine> (last visited 9/5/2021).

<sup>41</sup> 21 C.F.R. § 601.51(e) provides that after a biological product is licensed, the following information shall be made available for immediate disclosure absent extraordinary circumstances: “(1) All safety and effectiveness data and information. (2) A protocol for a test or study . . . (3) Adverse reaction reports, product experience reports, consumer complaints, and other similar data and information . . . (4) A list of all active ingredients and any inactive ingredients . . . (5) An assay method or other analytical method . . . (6) All correspondence and written summaries of oral discussions relating to the biological product file . . . (7) All records showing the manufacturer’s testing of a particular lot . . . (8) All records showing the testing of and action on a particular lot by the [FDA].”

<sup>42</sup> For the avoidance of doubt, this request includes but is not limited to all of the data and information in the biological product file, as defined in 21 C.F.R. § 601.51(a), for the Pfizer Vaccine enumerated in 21 C.F.R. § 601.51(e) with the exception of publicly available reports on the Vaccine Adverse Events Reporting System.

<sup>43</sup> All “Exhibits” referenced herein are attached to this Complaint.

35. On August 31, 2021, the FDA issued an acknowledgment and assigned case number 2021-5683 to the FOIA Request. (**Exhibit A.3.**)

**D. Request for Expedited Processing**

36. In the FOIA Request, PHMPT requested that the FDA process the FOIA Request on an expedited basis pursuant to 5 U.S.C. § 552(a)(6)(E)(v)(II).

37. On September 9, 2021, the FDA denied PHMPT's request for expedited processing of the FOIA Request (the "**Denial Letter**").<sup>44</sup> In the Denial Letter, the FDA stated in relevant part:

I have determined that your request for expedited processing does not meet the criteria under the FOIA. You have not demonstrated a compelling need that involves an imminent threat to the life or physical safety of an individual. Neither have you demonstrated that there exists an urgency to inform the public concerning actual or alleged Federal Government activity. Therefore, I am denying your request for expedited processing.

(**Exhibit A.4.**)

**ARGUMENT**

38. FOIA provides for "expedited processing of request for records" upon a showing of "compelling need." 5 U.S.C. § 552(a)(6)(E)(i)(II). When the person requesting information is "primarily engaged in disseminating information urgency to inform the public concerning actual or alleged Federal Government activity" constitutes a "compelling need" for expedited processing. 5 U.S.C. § 552(a)(6)(E)(v)(II).

39. PHMPT requested expedited processing of the FOIA Request on the basis that it is "primarily engaged in disseminating information" and that there is an "urgency to inform the public concerning actual or alleged Federal Government activity." In the Denial Letter, the FDA

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<sup>44</sup> The FOIA requires federal agencies to issue determinations on requests for expedited processing within ten days from the date of the request. 5 U.S.C. § 552(a)(6)(E)(ii)(I). The FDA's denial of PHMPT's request for expedited processing was issued 13 days after PHMPT issued the FOIA Request.

challenged PHMPT's request for expedited processing only on the basis that PHMPT allegedly failed to "demonstrate[] a compelling need that involves an imminent threat to the life or physical safety of an individual" or "that there exists an urgency to inform the public concerning actual or alleged Federal Government activity." As explained below, the FDA is wrong as there is an urgent need for the medical and scientific community and the public to review the data and information underlying the FDA's approval of the Pfizer Vaccine.

40. The FDA does not and cannot challenge that PHMPT is "primarily engaged in disseminating information." PHMPT is an organization made up of public health professionals, medical professionals, scientists, and journalists. PHMPT exists for the sole purpose of disseminating to the public the data and information in the biological product files for each of the COVID-19 vaccines. PHMPT intends to make any records produced in response to the FOIA request immediately available to the public through both its website and its individual members' platforms. Many of PHMPT's individual members, including all its members that are journalists, are primarily engaged in disseminating information to the public and do so across various



platforms, including through interviews,<sup>45</sup> articles,<sup>46</sup> blogs,<sup>47</sup> essays,<sup>48</sup> and podcasts.<sup>49</sup> Therefore, PHMPT and many of its members are “primarily engaged in disseminating information to the general public,” and, as explained below, there is a clear “urgency to inform the public concerning actual or alleged Federal Government activity,” here, the data and information underlying the licensure by the FDA of the Pfizer Vaccine.

41. In determining whether there is “urgency to inform the public,” courts consider: “(1) whether the request concerns a matter of current exigency to the American public; (2) whether the consequences of delaying a response would compromise a significant recognized interest; and (3) whether the request concerns federal government activity.” *Al-Fayed v. CIA*, 254 F.3d 300, 310 (D.D.C. 2001). All three factors are present here.

42. The FOIA Request concerns a matter of current exigency to the American public.

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<sup>45</sup> See, e.g., <https://www.foxnews.com/transcript/ingraham-angle-on-mask-mandates-bidens-failure-in-his-role> (Harvey Risch) (last visited 8/26/2021)

<sup>46</sup> See, e.g., <https://www.bmj.com/content/373/bmj.n1244> (Peter Doshi) (last visited 9/8/2021); <https://www.bmj.com/content/371/bmj.m4058> (Peter Doshi) (last visited 9/8/2021); <https://www.bmj.com/content/371/bmj.m4037> (Peter Doshi) (last visited 9/8/2021); <https://www.wsj.com/articles/are-covid-vaccines-riskier-than-advertised-11624381749> (last visited 8/25/2021); <https://www.wsj.com/articles/university-vaccine-mandates-violate-medical-ethics-11623689220> (Aaron Kheriaty and Gerard V. Bradley) (last visited 9/8/2021); <https://thefederalist.com/2021/07/05/how-college-covid-vaccine-mandates-put-students-in-danger/> (Andrew Bostom, Aaron Kheriaty, Peter A. McCullough, Harvey A. Rish, Michelle Cretella, and Gerard V. Bradley) (last visited 9/8/2021); <https://thefederalist.com/2021/08/18/why-forcing-unvaccinated-students-to-wear-cloth-masks-is-anti-science/> (Andrew Bostom, Gerard Bradley, Aaron Kheriaty, and Harvey Risch) (last visited 9/8/2021); <https://www.bmj.com/content/bmj/374/bmj.n1737.full.pdf> (Serena Tinari and Catherine Riva) (last visited 9/8/2021); <https://www.bmj.com/content/372/bmj.n627> (Serena Tinari) (last visited 9/8/2021); <https://ebm.bmj.com/content/early/2021/08/08/bmjebm-2021-111735> (Sarah Tanveer, Anisa Rowhani-Farid, Kyungwan Hong, Tom Jefferson, Peter Doshi) (last visited 9/8/2021); <https://www.arcdigital.media/p/medical-ethicist-sues-the-university> (Justin Lee) (last visited 9/8/2021).

<sup>47</sup> See, e.g., <https://blogs.bmj.com/bmj/2021/08/23/does-the-fda-think-these-data-justify-the-first-full-approval-of-a-covid-19-vaccine/> (Peter Doshi) (last visited 9/8/2021); <https://blogs.bmj.com/bmj/2020/11/26/peter-doshi-pfizer-and-modernas-95-effective-vaccines-lets-be-cautious-and-first-see-the-full-data/> (Peter Doshi) (last visited 9/8/2021). See also <https://www.re-check.ch/wordpress/en/covid-certificate/> (Catherine Riva and Serena Tinari) (last visited 9/8/2021).

<sup>48</sup> See <https://www.andrewbostom.org/2021/06/why-collegiate-covid-19-vaccine-mandates-are-lysenkoist-anti-science/> (Andrew Bostom) (last visited 9/8/2021).

<sup>49</sup> See, e.g., <https://www.andrewbostom.org/2021/05/dr-andrew-bostom-discusses-the-unfavorable-risk-benefit-ratio-of-covid-19-vaccination-of-very-low-covid-19-risk-12-to-17-year-olds-with-pfizers-emergency-use-authorization-only-mrna-vaccine/> (Andrew Bostom) (last visited 9/8/2021).

The FDA itself acknowledges this exigency in the Code of Federal Regulations, which expressly provides that “[a]fter a license has been issued, the following data and information in the biological product file are *immediately available for public disclosure* unless extraordinary circumstances are shown: (1) All safety and effectiveness data and information. . . .” 21 C.F.R. § 601.51(e) (emphasis added). The FDA’s own regulations thus expressly recognize the importance of having the data and information relied upon to license a vaccine “immediately available for public disclosure.” *Id.* The FDA’s regulation not only supports the need for expedited treatment under FOIA but is also an independent legal basis that requires expedited treatment of the FOIA Request.

43. This policy is not surprising given the FDA’s commitment to transparency and its entire program to assure transparency, because a lack of transparency erodes the confidence the medical and scientific community and the public have in the conclusions reached by the FDA.<sup>50</sup>

44. Beyond the FDA’s own regulations which admit the urgent need for transparency and immediate disclosure in this situation, there are two additional reasons that warrant expedited treatment of this request.

45. First, as explained above, there is an ongoing, public national debate regarding the adequacy of the data and information, and analyses of same, relied upon by the FDA to license the Pfizer Vaccine.

46. Although public health officials, media outlets, journalists, scientists, politicians, public figures, and others with large social or media platforms that have declared that the data and

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<sup>50</sup> <https://www.fda.gov/about-fda/transparency> (last visited 9/8/2021). As required by Congress, the FDA may only license vaccines that have been proven to be “safe and effective,” *see, e.g.*, 21 U.S.C. § 393, and the FDA makes this determination based on, *inter alia*, clinical trial reports provided by the sponsor which must be sufficient to demonstrate the product is both “safe” and “effective.” 21 C.F.R. 601.2(a). The FDA explains in its guidance materials that the clinical trials relied upon for approval are typically “1 to 4 years” (<https://www.fda.gov/patients/drug-development-process/step-3-clinical-research>) and the duration of clinical trials should “reflect the product and target condition.” <https://www.fda.gov/media/102332/download> (last visited 9/8/2021). *See also* <https://www.fda.gov/consumers/consumer-updates/it-really-fda-approved> (last visited 9/8/2021); <https://www.fda.gov/about-fda/what-we-do> (last visited 9/8/2021).



information underlying the licensure of the Pfizer Vaccine is more than sufficient for licensure,<sup>51</sup> numerous public health officials, media outlets, journalists, scientists, politicians, public figures, and others with large social or media platforms have publicly raised questions regarding the sufficiency of the data and information, the adequacy of the review, and appropriateness of the analyses relied upon to license the Pfizer Vaccine, including a number of the scientists and journalists that are members of PHMPT.<sup>52</sup>

47. The public debate is unlikely to be settled without full disclosure of the data and information underlying the FDA's conclusion that the Pfizer Vaccine is "safe and effective."

48. Given the widespread and ongoing public debate, the medical and scientific community and the public has an immediate need to review the data and information underlying the licensure of the Pfizer Vaccine. Public disclosure of this information will inform this ongoing public debate.

49. There is also an urgent need for the public to have immediate access to the data and information underlying the licensure of the Pfizer Vaccine because, over the objections of many, this product is being mandated to individuals across the country by the federal government,<sup>53</sup> local

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<sup>51</sup> See, e.g., *supra* ¶¶ 16-21.

<sup>52</sup> See, e.g., *supra* ¶¶ 22-27.

<sup>53</sup> See, e.g., <https://www.natlawreview.com/article/covid-19-vaccine-added-to-requirements-green-card-processing-effective-oct-1> (last visited 9/8/2021); <https://apnews.com/article/business-health-coronavirus-pandemic-coronavirus-vaccine-4cf7451267919302de4a7b591508e80c> (last visited 9/8/2021); <https://www.forbes.com/sites/joewalsh/2021/08/09/us-military-will-require-covid-vaccinations-by-mid-september/?sh=78defacd6c9f> (last visited 9/8/2021); <https://www.whitehouse.gov/briefing-room/statements-releases/2021/07/29/fact-sheet-president-biden-to-announce-new-actions-to-get-more-americans-vaccinated-and-slow-the-spread-of-the-delta-variant/> (last visited 9/8/2021).

governments,<sup>54</sup> public and private employers,<sup>55</sup> universities,<sup>56</sup> schools,<sup>57</sup> and various other institutions,<sup>58</sup> and many are expected to follow suit.<sup>59</sup>

50. During a time when COVID-19 vaccine mandates are being implemented<sup>60</sup> over

<sup>54</sup> See, e.g., <https://www.cnn.com/2021/08/12/us/san-francisco-vaccine-requirement/index.html> (last visited 9/8/2021); <https://www1.nyc.gov/site/doh/covid/covid-19-vaccines-keytonyc.page> (last visited 9/8/2021); <https://news.yahoo.com/orleans-now-requires-proof-vaccination-230433492.html> (last visited 9/8/2021).

<sup>55</sup> See, e.g., <https://www.cnn.com/2021/08/06/united-airlines-vaccine-mandate-employees.html> (last visited 9/8/2021); <https://sanfrancisco.cbslocal.com/2021/08/02/covid-kaiser-permanente-makes-vaccination-mandatory-for-all-employees/> (last visited 9/8/2021); <https://abcnews.go.com/Health/wireStory/walmart-mandates-vaccines-workers-headquarters-79177220> (last visited 9/8/2021); <https://www.kpbs.org/news/2021/aug/17/encinitas-covid-19-vaccine-negative-test-employees/> (last visited 9/8/2021); <https://www.cnn.com/2021/08/09/covid-vaccine-mandates-sweep-across-corporate-america-as-delta-surges.html> (last visited 9/8/2021); <https://www.reuters.com/business/energy/chevron-begins-covid-19-vaccination-mandates-wsj-2021-08-23/> (last visited 9/8/2021); <https://thehill.com/policy/healthcare/569051-pfizers-full-approval-triggers-new-vaccine-mandates> (last visited 9/8/2021); <https://cvshealth.com/news-and-insights/statements/cvs-health-will-require-covid-19-vaccinations-for-clinical-and-corporate-employees> (last visited 9/8/2021).

<sup>56</sup> See <https://universitybusiness.com/state-by-state-look-at-colleges-requiring-vaccines/> (last visited 9/8/2021). See also, e.g., <https://www.nbcnews.com/health/health-news/colleges-universities-covid-vaccination-mandates-facing-pushback-n1273916> (last visited 9/8/2021); <https://www.colorado.edu/covid-19/updates/covid-19-vaccination> (last visited 9/8/2021); <https://uhs.berkeley.edu/requirements/covid19> (last visited 9/8/2021); <https://huhs.harvard.edu/covid-19-vaccine-requirement-faqs> (last visited 9/8/2021); <https://www2.gmu.edu/safe-return-campus/vaccination-requirements> (last visited 9/8/2021); <https://www.pc.pitt.edu/news/vaccine-disclosure-requirements-2021-2022-campus-housing> (last visited 9/8/2021).

<sup>57</sup> See, e.g., <https://www.npr.org/sections/back-to-school-live-updates/2021/08/20/1029837338/a-california-school-district-mandates-vaccines-for-eligible-students> (last visited 9/8/2021); <https://patch.com/massachusetts/salem/salem-school-committee-approves-vaccine-mandate-sports-band> (last visited 9/8/2021); <https://www.nbcnewyork.com/news/coronavirus/nyc-will-require-vaccination-for-high-risk-school-sports/3232745/> (last visited 9/8/2021); <https://www.nj.com/hudson/2021/08/hoboken-believed-to-be-first-in-state-to-issue-mandate-for-students-12-and-up-get-vaccine-or-face-weekly-testing.html> (last visited 9/8/2021); <https://www.mercurynews.com/2021/08/19/la-county-school-district-mandates-covid-vaccines-for-k12-kids-others-soon-may-follow/> (last visited 9/8/2021).

<sup>58</sup> See, e.g., <https://www.reuters.com/world/us/new-york-city-mandates-covid-19-vaccine-public-school-teachers-staff-mayor-2021-08-23/> (last visited 9/8/2021); <https://www.cbsnews.com/news/california-covid-vaccine-teachers-mandate/> (last visited 9/8/2021); <https://www.nytimes.com/2021/08/18/us/washington-state-teacher-vaccine-mandate.html> (last visited 9/8/2021); <https://www.governor.ny.gov/news/governor-cuomo-announces-covid-19-vaccination-mandate-healthcare-workers> (last visited 9/8/2021); <https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/COVID-19/FAQ-Health-Care-Worker-Vaccine-Requirement.aspx> (last visited 9/8/2021); <https://www.nytimes.com/2021/08/09/us/washington-state-workers-vaccine-mandate.html> (last visited 9/8/2021); <https://www.denvergov.org/Government/COVID-19-Information/Public-Health-Orders-Response/News-Updates/2021/Mayor-Hancock-Announces-COVID-19-Vaccine-Requirement-for-Employees> (last visited 9/8/2021); See <https://www.bostonherald.com/2021/08/19/baker-issues-vaccine-mandate-for-42000-state-employees/> (last visited 9/8/2021).

<sup>59</sup> See <https://www.mississippifreepress.org/15126/fda-fully-approves-pfizer-biontech-vaccine-mandates-to-follow/> (last visited 9/8/2021); [https://www.huffpost.com/entry/vaccine-mandates-roll-out-fda-approval\\_n\\_6123e028e4b0df3eacd5d657](https://www.huffpost.com/entry/vaccine-mandates-roll-out-fda-approval_n_6123e028e4b0df3eacd5d657) (last visited 9/8/2021); [https://www.theadvocate.com/baton\\_rouge/news/coronavirus/article\\_9be6d02c-0434-11ec-b7b1-cb17d8495274.html?utm\\_medium=social&utm\\_source=twitternoladotcom&utm\\_campaign=snd](https://www.theadvocate.com/baton_rouge/news/coronavirus/article_9be6d02c-0434-11ec-b7b1-cb17d8495274.html?utm_medium=social&utm_source=twitternoladotcom&utm_campaign=snd) (last visited 9/8/2021). See also <https://www.latimes.com/california/story/2021-08-26/california-lawmakers-grapple-with-statewide-covid-19-vaccine-mandate> (last visited 9/8/2021).

<sup>60</sup> See, e.g., *supra* ¶¶ 28-32.

the objection of those that have questions about the data and information supporting the safety and efficacy of the Pfizer Vaccine, and individuals with these questions are being expelled from employment, school, transportation, restaurants, entertainment facilities, and the military, the public has an urgent and immediate need to have access to this data. The urgent need for the public to review this data is heightened by President Biden's recent announcement of vaccine mandates for millions of Americans, including employers with 100 or more employees, federal employees, and employees of federal contractors.<sup>61</sup>

51. PHMPT will forthwith disseminate any information it obtains in response to the FOIA Request. PHMPT, as an entity primarily engaged in disseminating information, has a recognized interest in timely contributing to the ongoing public debate regarding the adequacy of the data and information underlying the FDA's approval of the Pfizer Vaccine.

52. Finally, the information PHMPT seeks concerns actual or alleged federal government activity – namely, whether the FDA properly approved the Pfizer Vaccine based on adequate data and information. The FDA, which is committed to transparency, should immediately release the information PHMPT seeks in the FOIA Request.

53. Because the FDA denied PHMPT's request for expedited processing, PHMPT is entitled to immediately seek relief in this Court. 5 U.S.C. § 552(a)(6)(E)(iii).

### **Requested Relief**

WHEREFORE, Plaintiff prays that this Court:

- a. Provide for expeditious proceedings in this action;
- b. Enter an Order directing the FDA to produce all documents responsive to the FOIA Request on an expedited basis and in no event later than 10 days from the date of

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<sup>61</sup> <https://www.whitehouse.gov/covidplan/> (last visited 9/13/2021). See also <https://www.cnn.com/2021/09/09/politics/joe-biden-covid-speech/index.html> (last visited 9/13/2021).

any such order;

- c. Award Plaintiff its costs and reasonable attorneys' fees incurred in this action as provided by 5 U.S.C. § 552(a)(4)(E); and
- d. Grant such other and further relief as the Court may deem just and proper.

Dated: September 16, 2021

SIRI & GLIMSTAD LLP  
Aaron Siri (*pro hac vice* to be filed)  
Elizabeth Brehm (*pro hac vice* to be filed)  
Gabrielle Palmer (*pro hac vice* to be filed)  
200 Park Avenue  
17th Floor  
New York, New York 10166  
Tel: (212) 532-1091  
Fax: (646) 417-5967  
[aaron@sirillp.com](mailto:aaron@sirillp.com)  
[ebrehm@sirillp.com](mailto:ebrehm@sirillp.com)  
[gpalmer@sirillp.com](mailto:gpalmer@sirillp.com)

HOWIE LAW, PC

/s John Howie  
John Howie  
Texas Bar Number: 24027239  
2608 Hibernia Street  
Dallas, Texas 75204  
Tel: (214) 622-6340  
[jhowie@howielaw.net](mailto:jhowie@howielaw.net)

*Attorneys for Plaintiff*